Omlonti® (omidenepag isopropyl) – New drug approval

- On September 22, 2022, the FDA approved Santen's Omlonti (omidenepag isopropyl), for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OT).
- Omlonti is a relatively selective EP2 receptor agonist which decreases IOP.
- The efficacy of Omlonti was established in three randomized and controlled clinical studies in patients with OAG or OT with average baseline IOP of 24 to 26 mm Hg. The double-masked treatment duration was 3 months in all 3 studies. The third study included a 9-month open-label treatment period following the 3-month double-masked treatment period.
    - In the three studies, IOP reductions were observed for all treatment arms. In the Omlonti arm, the reduction in IOP ranged from 5 to 7 mm Hg across all three studies. The corresponding reductions for the timolol and latanoprost arms (other drugs used for OAG and OT) were 5 to 7 mm Hg and 6 to 8 mm Hg, respectively.
- Warnings and precautions for Omlonti include pigmentation; eyelash changes; ocular inflammation; macular edema; and risk of contamination and potential injury to the eye.
- The most common adverse reactions (≥ 1%) with Omlonti use were conjunctival hyperemia, photophobia, blurred vision, dry eye, instillation site pain, eye pain, ocular hyperemia, punctate keratitis, headache, eye irritation, and visual impairment.
- The recommended dose of Omlonti is one drop in the affected eye(s) once daily in the evening.
- Santen's launch plans for Omlonti are pending. Omlonti will be available as a 0.002% ophthalmic solution.